

Application No. 09/180,657
Amendment dated March 4, 2003
Reply to Office action of November 4, 2003

REMARKS

I. Status of the Claims

Claims 22-52, 55, 58-66, 68-74 and 93 are pending, with claims 22-51 withdrawn from consideration as directed to a non-elected invention. Claims 60, 62, 64-65 and 74 are said to be free of prior art; claim 93 is allowed.

Upon entry of this amendment, claims 61 and 62 are canceled and claims 52, 55, 58-60, 66, 70, 74 and 93 amended without prejudice or disclaimer. These claims are amended to focus on inventions of current commercial interest. New claims 95-106 are also introduced upon entry of this amendment.

The amended and new claims find support throughout the specification, including for example, the following sections:

| | |
|---------------------------------------|---|
| Claim 52, 58, 59, 98-100 and 104-106: | Page 9, lines 1-8; and examples 4, 5, 6, 10 and 11. |
| Claims 74 and 101: | Page 4, lines 7-9; and examples 4, 5, 6, 10 and 11. |
| Claims 95-97: | Example 4; page 26 (Table I); and page 39, line 24. |
| Claims 102-103: | Page 30, lines 4-10; and Fig. 5. |

II. Claim Rejections under 35 U.S.C. 102

Claims 52, 55, 58, 59, 61, 63, 66 and 68-73 are rejected for allegedly being anticipated by Sandoval (Archives of Biochemistry and Biophysics (1989) 271:157-167; "Sandoval"). Sandoval is said to discuss detection of increased levels of Lamp-1 protein in human fibroblasts from patients with I-cell disease, one type of LSD.

In response, it is noted that claim 52 as currently pending is directed to a method in which the LSD marker is assayed in a blood, serum, plasma or urine sample. Lamp-1 detection in Sandoval, in contrast, was detected in various inclusion bodies *within* fibroblast

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cells. Thus, for this reason alone, claim 52 and those claims depending on it are distinguished with respect to Sandoval. Furthermore, these claims are not obvious over Sandoval because the cited art contains no teaching or suggestion that the recited LSD markers could be detected in blood, plasma, serum or urine. Instead, it was thought that these recited LSD markers could only be detected intracellularly. The name Lamp, for example, reflects this understanding, standing for "lysosome-associated *membrane* protein." It is thus requested that this rejection be withdrawn.

New claim 95 and its dependent claims are directed to methods for detecting or monitoring the recited LSD markers in specific types of LSD that have not been discussed in the cited art. Claim 95, for example, does not include detection or monitoring methods with respect to I-cell disease. So for at least this reason, claim 95 and those claims that depend upon it are distinct from Sandoval.

New claim 102 is drawn to detection and monitoring methods that involve assaying for the level of Lamp-2. Methods encompassing Lamp-2 were previously pending but rejected for lacking enablement (see, Office Action mailed August 30, 2000). The Office Action specifically took the position that the specification taught that although Lamp-2 levels were increased in some individuals having a LSD, the levels in a number of other LSD patients decreased or was unchanged. New claim 102, however, focuses on methods for detecting or monitoring only those lysosomal storage disorders in which Lamp-2 is increased (see, e.g., Fig. 5), thus addressing this concern.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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